

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
10/084,578	02/27/2002	James L. DiGuiseppi	9250-29	6023			
20792	7590 01/11/2005		EXAMINER				
MYERS BIO PO BOX 3742	GEL SIBLEY & SAJO 28	LEARY, L	LEARY, LOUISE N				
RALEIGH, N		ART UNIT	PAPER NUMBER				
			1654				

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicat	on No.	Applicant(s)				
		10/084,5	78	DIGUISEPPI ET AL.				
	Office Action Summary	Examine	r	Art Unit				
		Louise N		1654				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1) 又	Responsive to communication(s) file	d on <u>8-23-2004</u> .						
, —		·						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
 4) Claim(s) 1-28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-28 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 								
Applicati	on Papers							
	The specification is objected to by the							
10)⊠ The drawing(s) filed on <u>27 February 2002</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority under 35 U.S.C. § 119								
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 								
2) Notice 3) Information	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (P mation Disclosure Statement(s) (PTO-1449 or r No(s)/Mail Date		4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate	O-152)			

Art Unit: 1654

1. Claims 1-28 are pending in this application.

2. The Examiner acknowledges receipt of applicant's Request for Continued Prosecution and "REMARKS/ARGUMENTS" filed August 19, 2004.

The "REMARKS/ARGUMENTS" filed August 19, 2004 are being held in abeyance in favor of the official office action on the merits given below.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 5,164,796. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a container; (b) a filter or means for filtering; and a sensor means. Both inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or instrument claimed. The devices or instruments claimed in each invention measure changes in the presence of "CO₂" while detecting or monitoring the growth of

Art Unit: 1654

microorganisms. Hence, the devices or instruments claimed in both inventions perform identical or closely analogous functions. In addition, the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made. Specifically, the instant invention claims "a) a container defining a chamber therein and having an inlet and outlet in fluid communication with said chamber; b) a filter mounted in said chamber between said inlet and said outlet; and c) a sensor..." Both invention claimed closely analogous methods that use the devices claimed. It is noted that the open-ended ---comprising---- language used to describe the structural means of the instruments claimed in U.S. Patent No. 5,164,796 encompasses a "container" and a "filter" means having the structural features described in the instant device claims and the methods of both inventions use a device comprising semi-permeable membranes or compositions. As a result, there is substantial overlap of the subject matter claimed in both inventions.

II. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,094,955.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a container; (b) a filter or means for filtering; and a sensor means. Both inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or

Art Unit: 1654

instrument claimed. The devices or instruments claimed in each invention measure changes in the presence of "CO2" while detecting or monitoring the growth of microorganisms. Hence, the devices or instruments claimed in both inventions perform identical or closely analogous functions. In addition, the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made. Specifically, the instant invention claims "a) a container defining a chamber therein and having an inlet and outlet in fluid communication with said chamber; b) a filter mounted in said chamber between said inlet and said outlet; and c) a sensor..." Both invention claimed closely analogous methods that use the devices claimed. It is noted that the open-ended ---comprising--- language used to describe the structural means of the instruments claimed in U.S. Patent No. 5,094,955 encompasses a "container" and a "filter" means having the structural features described in the instant device claims and the methods of both inventions use a device comprising semi-permeable membranes or compositions. As a result, there is substantial overlap of the subject matter claimed in both inventions.

III. Claims 22-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,217,876.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a container; (b) a

Art Unit: 1654

filter or means for filtering; and a sensor means. Both inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or instrument claimed. The devices or instruments claimed in each invention measure changes in the presence of "CO₂" while detecting or monitoring the growth of microorganisms. Hence, the devices or instruments claimed in both inventions perform identical or closely analogous functions. In addition, the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made. Specifically, the instant invention claims "a) a container defining a chamber therein and having an inlet and outlet in fluid communication with said chamber; b) a filter mounted in said chamber between said inlet and said outlet; and c) a sensor..." Both invention claimed closely analogous methods that use the devices claimed. It is noted that the open-ended ---comprising--- language used to describe the structural means of the instruments claimed in U.S. Patent No. 5,217,876 encompasses a "container" and a "filter" means having the structural features described in the instant device claims and the methods of both inventions use a device comprising semi-permeable membranes or compositions. As a result, there is substantial overlap of the subject matter claimed in both inventions.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise N. Leary Primary Examiner Art Unit 1654 January 8, 2005